VA Pittsburgh Healthcare System Research and Development

POLICY NUMBER: 002
APPROVAL DATE: 2/9/2010
EFFECTIVE DATE: 2/9/2010

TITLE: Honest Broker Policy

1.0 PURPOSE

This policy describes the processes to be used when using an honest broker to de-identify PHI associated with research data, tissue samples, and/or specimens. It also describes the requirements and responsibilities of an honest broker.

2.0 REVISION HISTORY

Date	Revision #	Change	Reference Section(s)
Feb 9, 2010		New policy/procedure	

3.0 SCOPE

This policy applies to all human subject research activities conducted at or under the auspices of the VA Pittsburgh Healthcare System (VAPHS).

4.0 POLICY

The VA Pittsburgh Healthcare System Office of Research and Development is committed to safeguarding the Protected Health Information (PHI) of all veterans who participate in research conducted under the jurisdiction of the VAPHS IRB. It is the policy of the VAPHS IRB to comply with the Health Insurance Portability and Accountability Act (HIPAA) which can be found at 45 CFR Parts 160 and 164 or at http://aspe.hhs.gov/admnsimp/final/PvcTxt01.htm, as well as VHA Handbook 1605.1, Privacy and Release of Information. Under the Privacy Rule and VHA Handbook 1605.1, PHI may be used and disclosed without patient permission when the PHI is considered de-identified. For research purposes, PHI may be de-identified by an honest broker which is affiliated with VAPHS [i.e., VA employee, Without Compensation (WOC)_employee, or contracted services]or by a non-affiliated honest broker, provided that a Business Associate Agreement has been properly executed.

An honest broker is an individual, organization or system acting for, or on behalf of VAPHS to collect and provide health information to research investigators whereby it would not be reasonably possible for the investigators or others to identify the patient/subjects directly or indirectly. Additionally, an honest broker can be used to verify that PHI associated with any tissue samples and/or other human biological specimens are devoid of individually identifiable information. The information may be provided as completely de-identified or in the form of a limited data set. If the health information is provided as a limited data set, the investigators must also complete and obtain approval of a Data Use Agreement.

Information provided to the investigators by the honest broker may incorporate a code to permit information collation or subsequent inquiries, however, the linkage code must be maintained by the honest broker, and any codes provided to the investigators must be in compliance with VHA Handbook 1605.1, Appendix B.§3. Individuals serving as an honest broker must have legitimate access to the data requested by the investigator and they must be completely independent of the research team. The honest broker must be named in the Institutional Review Board protocol and must sign an honest broker certification form as outlined in Section 5.0.

HIPAA describes multiple data elements that must be removed from health information in order for the information to be considered de-identified. Therefore, in order for a data set to be considered de-identified it must meet the following criteria:

1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable applying such principles and methods, determines that the risk is very small that the information could be used alone, or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is subject of that information, and this person documents the methods and results of the analysis that justify such a determination; or

2. The following identifiers of the individual, his or her relatives, employers, or household members have been removed:

   a. Names
   b. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census
      i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
      ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
   c. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
   d. Telephone numbers;
   e. Fax numbers;
   f. Electronic mail addresses;
   g. Social Security numbers;
   h. Medical record numbers;
   i. Health plan beneficiary numbers;
   j. Account numbers;
   k. Certificate/license numbers;
   l. Vehicle identifiers and serial numbers, including license plate numbers;
   m. Device identifiers and serial numbers

    n. Web Universal Resource Locators (URLs);
    o. Internet Protocol (IP) address numbers;
    p. Biometric identifiers, including finger and voice prints;
    q. Full face photographic images and any comparable images; and
    r. Any other unique identifying number, characteristic, or code; and

AND the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

As an alternate option, HIPAA also permits, without prior patient authorization the use and disclosure of health information for research purposes in the form of a limited data set. A limited data set is protected health information which **excludes** the following identifiers of the individual, his or her relatives, employers, or household members:

    a. Names;
    b. Postal address information, other than town or city, State, and zip code;
    c. Telephone numbers;
    d. Fax numbers;
    e. Electronic mail addresses;
    f. Social security numbers;
    g. Medical record numbers
    h. Health plan beneficiary numbers;
    i. Account numbers
    j. Certificate/license numbers;
    k. Vehicle identifiers and serial numbers, including license plate numbers;
    l. Device identifiers and serial numbers;
    m. Web Universal Resource Locators (URLs);
    n. Internet Protocol (IP) address numbers
    o. Biometric identifiers, including finger and voice prints; and
    p. Full face photographic images and any comparable images.

The use of the VAPHS IRB-certified Honest Broker System ensures compliance with the Federal Policy Common Rule, VAPHS IRB regulations and the HIPAA Privacy rule. The use of the VAPHS Honest Broker System is not mandatory for those studies for which all data remain within the VA entity. However, use of the system is mandatory for those studies for which de-identified data are stored, transmitted, or transferred outside of the VA entity. A VAPHS certified Honest Broker must certify that data are truly de-identified prior to the storage/transfer of research data outside of the VA entity.

The Privacy Rule allowance permitting de-identified PHI to be used without patient authorization is relevant for research studies in the following circumstances:

1. Those studies seeking an exemption from the federal regulations under 45 CFR §46.101(b)(4) when all medical record information *is in existence* at the time of the IRB submission – "Research involving the collection or study of existing data, documents, records, pathological

specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." The honest broker system ensures that the investigator is neither interacting with the individuals nor recording identifiable information about them.

2. Those studies meeting the criteria for "no human subjects involvement" (45 CFR 46.102.F) and ***all data are not currently available*** – "Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction with the individual, or 2) Identifiable private information. In this case, the honest broker can assign a code number to the data given to the investigator provided that the investigator does not have access to the information linking this code number to the identities of the respective patients. Using the code number, the investigator can request through the honest broker, additional medical information corresponding to a specific patient. For IRB purposes, a study of this type would meet the criteria for "no human subjects" involvement (45 CFR 46.102.f) because the investigators have neither interacted nor intervened with the subjects for research purposes and the use of the honest broker ensures that the investigators will not obtain private identifiable information. The determination regarding "no human subjects" must be made by the IRB using the VAPHS Human Subject Determination Checklist.

3. The Honest Broker System may be used to identify eligible patients for subsequent recruitment into clinical trials. Based on defined search criteria, the honest broker would provide a de-identified listing of the health information of potentially eligible subjects, to include re-identification code numbers, to the clinical trial investigators. The investigators would then determine which of these patients appear to meet eligibility criteria and convey the respective re-identification code numbers back to the honest broker. The honest broker would then provide the names of the identified patients to the patients' personal physicians who would contact the patients to 1) introduce the research study; 2) ascertain their interest in study participation and 3) instruct the patients to contact directly the investigators or obtain their written authorization to share their interest in study participation with the investigators and be contacted by the investigators.

5.0 PROCEDURES

5.1 System/Process Approval Procedures

The System(s)/Process(es) that will be utilized must be approved by the VAPHS IRB and the VAPHS Privacy Officer. An Honest Broker System/Process can be project specific, or may be more general and applicable to multiple protocols falling under a particular Center, Department, etc. In order to seek approval, the Application for the Certification of Honest Broker Systems/Processes form must be submitted to the VAPHS IRB. This application is available on the VAPHS research website at http://www.vaphs.research.med.va.gov/. This application must be submitted VAPHS IRB Chair for approval, after which time it will be forwarded to the VAPHS Privacy Officer and ACOS/R&D for approval. Approvals will be

granted based upon the determination that there is sufficient evidence to meet or exceed the following certification criteria:

    a.   There is written documentation of the processes and/or systems that will be used to develop fully de-identified health information data sets and/or limited data sets. This documentation must address both electronic and paper-based records.

    b.   There is written documentation of policies and procedures necessary for compliance with the HIPAA Privacy Rule, the Federal Policy regulations for human subject protections (45 CFR 46) and applicable VA Data Security and Privacy policies.   In addition, the Privacy Officer must ensure that adequate procedures are in place for the security and management of all PHI in the honest broker's possession during the performance of honest broker functions.

    c.   There is written documentation of auditing and quality checks related to determining the efficacy of de-identification mechanisms.

    d.   There is written documentation for the ongoing security and management of re-identification or linkage codes.

    e.   Each individual named in the application who will be providing honest broker services has been approved by the ACOS/R&D or designee as a Certified Honest Broker. Procedures related to the honest broker certification process are outlined in Section 5.2.

5.2. Honest Broker Credentialing Procedures

    a. Each individual providing honest broker services must submit a one-time application to the VAPHS Research Office. The application consists of the following:

        i.   A signed and dated Honest Broker Credentialing Request form

        ii.   A current (within 1 year) Curriculum Vitae (CV) or Resume

        iii.   Evidence of having completed the required VAPHS Honest Broker Training Course and Post-Test on Data Security and Privacy Issues. The Honest Broker candidate must achieve a score of 90% or greater to qualify for certification.

    b. Applications will be reviewed by the ACOS/R&D or designee and written proof of certification will be provided to the applicant.

5.3 Project-Specific Procedures

Once an investigator has a project for which he would like to enlist the services of a VAPHS Honest Broker, the protocol must be submitted to the VAPHS IRB and the following conditions must be met before the services can be implemented:

    a. There is documented evidence that the process used to de-identify or render a data set a limited data set has been approved by the VAPHS IRB and the VAPHS Privacy Officer (as described in Section 5.1)

    b. The honest broker must be named in the research protocol and a description of the information to be provided by the honest broker must be provided.

    c. There is documented evidence that the honest broker has been credentialed by the VAPHS ACOS/R&D, or designee (described in Section 5.2 above)

    d. A signed and dated Honest Broker Agreement must be submitted to the IRB.

e. The research protocol has received the approval of all appropriate subcommittees, the R&D Committee and a letter indicating that the study may be initiated has been issued by the VAPHS Associate Chief of Staff for Research and Development.

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